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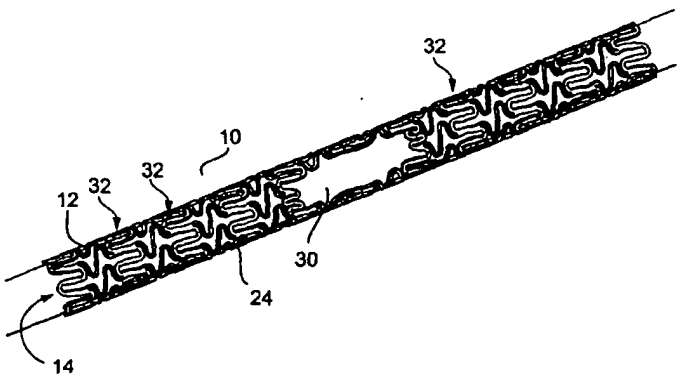

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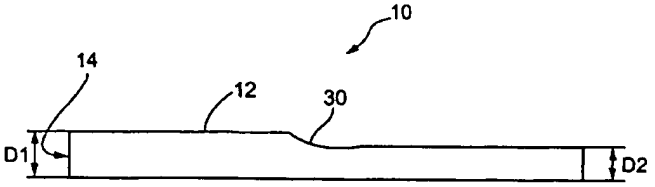

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(57) Abstract: A stent design (10) is provided for placement at a bifurcation, which provides support and coverage of a vessel. The stent (10) has ring sections made up of expansion segments arranged circumferentially around the stent (10), each of the expansion segments having a narrow strut and a wide strut joined by a joining segment, wherein the joining segment is alternatingly located at one end of the narrow and wide struts for one expansion segment, and at another end of the narrow and wide struts for another expansion segment. The ring sections are connected to one another by a series of sinusoidal connectors. Struts and connectors are non-parallel to axes of the stent. Optionally, a side hole (30) is provided for ease of access into a branch vessel.

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STENT FOR VESSEL SUPPORT, COVERAGE AND SIDE BRANCH ACCESSIBILITY

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to the field of medical stents and, more particularly, to a stent featuring struts and connectors which are arranged in specific configurations and optionally including at least one side opening for alignment with an ostium of a branch vessel in the region of a vessel bifurcation.

A stent is a type of endoprosthesis device, typically intraluminally placed or implanted within a vein, artery, or other tubular body organ for treating an occlusion, stenosis, aneurysm, collapse, dissection, or weakened, diseased, or abnormally dilated vessel or vessel wall, by expanding the vessel or by reinforcing the vessel wall. In particular, stents are quite commonly implanted into the coronary, pulmonary, neurovascular, peripheral vascular, renal, gastrointestinal and reproductive systems, in order to reinforce individual body organs. Current applications for stents include improving angioplasty results by preventing elastic recoil and remodeling of the vessel wall and for treating dissections in blood vessel walls caused by balloon angioplasty of coronary arteries as well as peripheral arteries. Conventional stents have been used for treating more complex vascular problems, such as lesions at or near bifurcation points in the vascular system, where a secondary artery branches out of a larger, main artery, with limited success rates, as described by Chevalier, B., *et al.*, in *The American Journal of Cardiology*, 82(8): 943-949, 1998; Yamashita, T., *et al.*, in *Journal of the American College of Cardiology*, 35(5): 1145-1151, 2000; and Satler, L.F., *et al.*, in *Catheterization and Cardiovascular Interventions*, 50 (4): 406-410, 2000.

Prior art relating to conventional stent technology is relatively well developed. A first example of a stent design is disclosed by Palmaz, in U.S. Patent No. 5,102,417, wherein the stent is described as consisting of a series of elongated tubular members having a plurality of slots disposed substantially parallel to the longitudinal axis of the tubular members. The tubular members are connected by at least one flexible connecting member.

A second example of a stent design is disclosed by Israel, in U.S. Patent No. 5,733,303, wherein the stent is described as consisting of a tube having a patterned shape, which has first and second meander patterns. The even and odd first meander patterns are 180 degrees out of phase, with the odd patterns occurring between every two even patterns. The second meander patterns are intertwined with the first meander patterns and may also be formed of even and odd patterns.

A third example of a stent design is disclosed by Lau, in U.S. Patent No. 5,728,158, wherein the stent is described as consisting of a plurality of spaced apart cylindrical elements positioned along a longitudinal axis, where each of the cylindrical elements consist of ribbon-like material disposed in an undulating pattern. This stent design also includes a plurality of connecting members for connecting adjacent cylindrical elements.

Another example of a stent design is disclosed by Jang, in U.S. Patent No. 5,948,016, wherein the stent is described as a first and second expansion column having a plurality of first and second expansion column slots that are formed of a plurality of first and second expansion struts, where the slots are non-parallel to the longitudinal axis of the stent.

A further example of a stent design is disclosed by Fischell, in U.S. Patent No. 6,190,403, wherein the stent has adjacent flexible links around the circumference of the stent which are designed to nest one into the other, allowing the stent to be able to crimp down without overlap onto a low profile balloon.

These and other stent designs have a variety of drawbacks, in that some of them do not sufficiently account for the tradeoff between vessel coverage and support, and potential medical risk. It is generally believed that the higher the stent material to surface ratio, the better the vessel coverage and support, but the higher the risk of restenosis (re-narrowing of the treated vessel) or other complications. Other problems associated with prior art stents include an inability to negotiate through a tortuous vessel due to rigidity, foreshortening of the stent during expansion, an inability to crimp the stent onto the balloon with a low profile, and an inability to access side branch vessels.

One problem encountered when using conventional stents at a bifurcation is stent jailing. Stent jailing occurs when the struts of a stent cross the ostium of a side-branch vessel. It is believed that blocking the ostium of the side branch by

deploying the stent in the main branch may contribute to thrombosis. In addition, if a stent is placed in the main branch the physician will be unable to gain access to the side branch without deforming the stent in the main branch. To avoid this problem, the physician often will deploy a stent in the side branch first, and then deploy a second stent in the main branch, covering the ostium of the side-branch artery. There is evidence that such dual-stenting causes increased risk of myocardial infarction or restenosis. Stent jailing can result in both acute and chronic side branch artery occlusion (in an estimated 12%-40% of cases) due to partial obstruction by the stent struts, plaque shifting and flow disturbances.

There is thus a widely recognized need for, and it would be highly advantageous to have, a stent devoid of the above limitations.

SUMMARY OF THE INVENTION

According to one aspect of the present invention there is provided a stent having a longitudinal axis, wherein the stent has a first ring section made up of expansion segments arranged circumferentially around the stent, each of the expansion segments having a first strut and a second strut joined by a joining segment. The joining segment is alternatingly located at one end of the first and second struts for one expansion segment, and at another end of the first and second struts for another expansion segment, and the first strut is not parallel to the longitudinal axis of the stent. The stent further includes a second ring section made up of expansion segments arranged circumferentially around the stent, each of the expansion segments having a first strut and a second strut joined by a joining segment. The joining segment is alternatingly located at one end of the first and second struts for one expansion segment, and at another end of the first and second struts for another expansion segment, and the first strut is not parallel to the longitudinal axis of the stent. The stent further includes a series of sinusoidal connectors for connecting the first ring section to the second ring section, the connectors having a first section, a second section and a third section, each of the connectors having a first end and a second end, wherein the first end is connected to a second strut of an expansion segment of the first ring forming a first connection point, and the second end is connected to a second strut of an expansion segment of the second ring forming a second connection point. According to one aspect of the present invention, the first ring section is offset from

the second ring section and the said second section of the connector is not perpendicular to the longitudinal axis of the stent.

According to another aspect of the invention, there is provided a stent having a stent body and a lumen, wherein the stent body has a ring section made up of expansion segments arranged circumferentially around the stent, each of the expansion segments having a first strut and a second strut joined by a joining segment, wherein the joining segment is alternatingly located at one end of the first and second struts for one expansion segment, and at another end of the first and second struts for another expansion segment, and wherein the first and said second struts are comprised of an upper curved portion, and a lower curved portion connected to the upper curved portion.

According to yet another aspect of the invention, there is provided a stent having a configuration of cells made up of struts and connectors, wherein the cells are rotationally symmetrical and linearly asymmetrical, and wherein the struts and connectors are arranged in an eccentric pattern.

According to further features in preferred embodiments of the invention described below, the struts are non-parallel to the longitudinal axis.

According to yet another aspect of the present invention, the first and second connection points are aligned with the longitudinal axis.

According to yet another aspect of the present invention, the stent further includes a side hole which is different than the cells. The difference may be shape, or size, and in a preferred embodiment, the side hole is larger than the cells.

According to yet another aspect of the present invention, the stent has different diameters proximal to and distal to the side hole when it is in its crimped state.

According to yet another aspect of the present invention, the stent has side hole cells in a region of the side hole, wherein the side hole cells are of a different geometrical configuration than the cells. According to a preferred embodiment, the side hole cells are of the same geometrical configuration as the cells.

According to other aspects of the present invention, the first struts are wider than the second struts, they are curved, and they are non-parallel to each other.

According to yet other aspects of the present invention, the struts may vary over their lengths in thickness and width. Further, the struts can be straight or curved or a combination of both, or irregularly shaped.

According to another aspect of the present invention, the joining segments are "C" shaped and non-parallel to a circumferential axis.

According to yet other aspects of the present invention, the connectors have a relatively straight middle portion, and the middle portion is non-parallel to a circumferential axis.

According to yet another aspect of the present invention, the stent has a drug placed thereon. The drug may be an HDAC inhibitor, and may be incorporated into a biocompatible polymer.

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, suitable methods and materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and not intended to be limiting.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only, and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the invention may be embodied in practice.

In the drawings:

FIG. 1A is a schematic diagram illustrating a preferred embodiment of the stent in its pre-expanded state, optionally including a side opening, in accordance with the present invention;

FIG. 1B is a schematic diagram illustrating the stent of FIG. 1A having two diameters in its crimped state;

FIG. 2 is a planar view of the stent geometry according to a preferred embodiment of the present invention;

FIGS. 3A-3C are views of the stent geometry according to several configurations, in accordance with the present invention;

FIG. 4 is a planar view of a stent geometry according to another preferred embodiment of the present invention;

FIGS. 5A and 5B are expanded views of the stent of FIGS.1-4, showing struts, connectors, joining segments and cells after expansion;

FIG. 6 is a schematic diagram illustrating a stent design according to another embodiment of the present invention;

FIG. 7 is a close-up view of the stent geometry shown in FIG. 6;

FIG. 8 is an expanded view of the stent geometry shown in FIGS. 6 and 7;

FIGS. 9A-9B are schematic illustrations of one embodiment of the side hole, in an unexpanded and expanded state;

FIGS. 10A-10B are schematic illustrations of another embodiment of the side hole, in an unexpanded and expanded state;

FIG. 11A-11B are schematic illustrations of yet another embodiment of the side hole, in an unexpanded and expanded state; and

FIG. 12 is an illustration of a catheter and delivery system, for delivery of the stent of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is of a stent featuring struts, joining segments and connectors which are arranged in specific configurations and optionally including at least one side opening for alignment with an ostium of a branch vessel in the region of a vessel bifurcation.

Specifically, the present invention can be used to treat a variety of vascular disorders, including those occurring in regions of vessel bifurcations.

The principles and operation of a stent according to the present invention may be better understood with reference to the drawings and accompanying descriptions.

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of the components set forth in the following

description or illustrated in the drawings. The invention is capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

For the purposes of the following description, the term "unexpanded" is to be understood to mean the design of the stent once it is cut, and should not be confused with the term: "crimped state," which refers to the configuration of the stent after it is crimped onto a balloon or any other expander. In addition, the stent may be made of self-expanding material, or may expand by any other method.

Referring now to the drawings, FIGS. 1A and 1B illustrates one preferred embodiment of the stent, optionally including at least one side opening. In FIG. 1A, the stent, hereinafter referred to as stent 10, of the present invention, features a stent body 12 and a lumen 14. Stent body 12 is generally of a variable three-dimensional geometrical configuration having variable dimensions (for example, length, diameter, thickness). Stent body 12 can be made of titanium, stainless steel, biocompatible polymers, or any other material suitable for implantation. Lumen 14 represents the inner volumetric space bounded by stent body 12.

As shown in FIG. 1B, which is an illustration of stent 10 in its crimped state, stent 10 also has a side hole 30, which will be described in greater detail hereinbelow. It should be readily apparent that the side hole is optional, and that many different types of side hole are possible, and more than one side hole can be included, as will be described in greater detail further hereinbelow. Furthermore, in a preferred embodiment, the section of stent body 12 proximal to side hole 30 has a greater diameter (D1) and is more oval than the diameter (D2) of the section of stent body 12 distal to side hole 30. This difference in diameter is useful both in a crimped state, due to the presence of a side sheath for side branch access, as described further hereinbelow, and in an expanded state, to account for a difference in the diameter of a vessel distal and proximal to a bifurcation.

Referring now to the details of stent geometry, reference is made to FIG. 2, which shows a first preferred embodiment of the stent geometry in its unexpanded state. Stent body 12 features a first directional axis and a second directional axis, wherein the first directional axis is perpendicularly disposed relative to the second directional axis. In particular, the first directional axis is a longitudinal axis 16,

extending along the length of stent body 12, and the second directional axis is a circumferential axis 18. As shown in the planar view of FIG. 2, circumferential axis 18 lies perpendicular to longitudinal axis 16. It should be understood that in a tubular view, as shown in FIG. 1A, many circumferential axes exist around the circumference of stent 10, any of which may be considered circumferential axis 18.

Stent body 12 has a cellular configuration featuring a repeating pattern of ring sections 32 and connectors 24 connecting the ring sections to one another. Each ring section 32 includes several expansion segments 33, each of which includes a first strut 20 and a second strut 22, connected on one end by a joining segment 21. First struts 20 and second struts 22 may vary in both width and in thickness, and may have changing dimensions over their lengths. Furthermore, first struts 20 and second struts 22 may be straight or curved, and may have a combination of straight and curved sections, or they may have completely irregular shapes. Within each ring section 32, the joining segment 21 is located at alternating ends of the expansion segment 33. In a preferred embodiment, joining segment 21 is curved, for example, "C" shaped, which may help provide additional radial support and strength. In alternative embodiments, joining segment 21 is straight or has a combination of curved and straight sections, or a combination of thicknesses or widths.

In a preferred embodiment, connectors 24 are sinusoidal, as shown in FIG. 2. Sinusoidal is defined as having a curved up and down pattern, and does not imply an actual mathematical configuration. Connectors 24 have two end portions 36, 38 with a middle segment 40 in between the two end portions 36, 38. In a preferred embodiment, end portions 36, 38 are curved. In a preferred embodiment, middle segment 40 is relatively straight. However, it should be readily apparent that middle segment 40 may be partially or totally curved as well. Middle segment 40 is not parallel to a circumferential axis 18 of the stent 10. Middle segment 40 is preferably slanted so as to enable connectors to fit closely together without touching one another, thus enabling tighter crimping of the stent 10.

In the preferred embodiment illustrated in FIG. 2, connectors 24 are attached at one end of a second strut 22 of one ring section 32 to a second strut 22 of another ring section 32, forming a first attachment point 42 and a second attachment point 44, respectively. Thus, second struts 22 generally have connectors 24 at both ends, while first struts 20 do not have connectors 24 attached to them. In alternative

embodiments, connectors 24 are attached to first struts 20, alone or in combination with second struts 22.

In the preferred embodiment shown in FIG. 2, the attachment points 42 and 44 are located relatively close to a point at which joining segment 21 begins. In different embodiments, the attachment points may be located at any distance from joining segment 21 or on joining segment 21, rather than on struts 20, 22. Furthermore, the attachment points may vary in location from strut to strut. Ring sections 32 are offset from one another in the circumferential direction by an amount defined by the locations of the attachment points of the connectors. In one embodiment, the amount of offset is in a range of 0.1-1 mm. In a preferred embodiment, the amount of offset is approximately 0.4 mm.

Cells 25 are formed by the plurality of first struts 22, second struts 20, joining segments 21 and connectors 24. Struts 20, 22, joining segments 21, connectors 24 and cells 25 are each of a variable geometrical configuration having variable dimensions (length, width, height). Optional side hole 30, as shown in FIG. 1, has different characteristics than any of the other plurality of cells 25, distinguishing it as a unique structure in this regard. It is generally larger than any of cells 25, and it has a different shape than any of cells 25.

As shown in FIG. 2, each of the plurality of struts 20, 22, joining segments 21, ring sections 32, and connectors 24, is oriented at an angle with respect to both a longitudinal axis 16 and a circumferential axis 18 of stent body 12. In alternative embodiments, struts 20 and 22 and joining segments 21 are curved or irregularly shaped and thus, not at specific angles with respect to the axes. Furthermore, in several embodiments, first and second strut 20 and 22 are not parallel to each other. In one embodiment, first strut 20 is oriented at an angle between zero and 360 degrees with respect to longitudinal axis 16, and second strut 22 is oriented at an angle between zero and 360 degrees with respect to longitudinal axis 16. In one preferred embodiment, the angle of first strut 20 is between 340 and 350 degrees (or between –10 and –20) and the angle of second strut 22 is between 350 and 360 degrees (or between 0 and –10 degrees). In a preferred embodiment, the angle of first strut 20 is 346 degrees (or –14 degrees) with respect to longitudinal axis 16, and second strut 22 is 352 degrees (or –8 degrees) with respect to longitudinal axis 16. In alternative embodiments, the angle of first strut 20 is approximately 10 degrees and the angle of

second strut 22 is approximately 30 degrees. The angles of first and second struts 20 and 22 may be the same with respect to longitudinal axis 16, but they do not have to be the same. Various combinations of angles are envisioned. Accordingly, each of the plurality of struts 20, 22 is oriented as non-parallel to a longitudinal axis 16.

In one embodiment, the angle of joining segment 21 is in a range of 0 to 180 degrees from circumferential axis 18. In another embodiment, joining segment 21 is curved, and thus cannot be considered either parallel or perpendicular to any axis. In one embodiment, middle section 40 of connector 24 is a relatively straight line, and is oriented at an angle between 0 and 180 degrees with respect to circumferential axis 18. In one embodiment, middle section 40 is oriented at an angle in a range of 5-25 degrees with respect to circumferential axis 18. In a preferred embodiment, middle section 40 is oriented at 18 degrees with respect to circumferential axis 18.

In one embodiment, ring sections 32 are not parallel to a circumferential axis 18 of stent body 12. Specifically, ring sections 32 are oriented at an angle between zero and ninety degrees with respect to circumferential axis 18. In a preferred embodiment, ring sections 32 are parallel to circumferential axis 18.

It should be readily apparent that many different configurations of struts 20, 22, connectors 24 and joining segments 21 are possible, all of which fall within the scope of the invention. As shown in FIGS. 3A-3C and FIG. 4, any of these elements may be longer, shorter, wider, narrower, curved or straight or any combination thereof, thicker, thinner, and angled differently while still maintaining the basic embodiment.

Reference is now made to FIG. 4, which shows another aspect of the first preferred embodiment of stent 10 shown in FIG. 1. In this embodiment, first strut 20 is narrower than second strut 22. In one embodiment, first strut 20 is between 0.13 and 0.14 mm at its widest point, and second strut 22 is between 0.15 and 0.16 mm at its widest point. In a preferred embodiment, at its widest point, first strut 20 is 0.135 mm and second strut 22 is 0.155 mm. Furthermore, as shown in FIG. 4, first and second attachment points 42 and 44 are aligned with one another between adjacent expansion rings 32, and, in a preferred embodiment, are also aligned with a longitudinal axis 16 of stent 10. This provides added flexibility for stent 10 as it makes its way through often-tortuous blood vessels in its crimped state. For this reason, expansion rings 32 within stent 10 are not able to rotate relative to each other.

While the sinusoidal configuration of connectors 24 allows for some flexibility, more flexibility and ease of manipulation is believed to be possible when attachment points 42 and 44 are aligned, because this arrangement prevents torque forces from diminishing the effectiveness of the forces necessary for navigation.

In a preferred embodiment, attachment points 42 and 44 are attached to the wider second strut 22, and the narrower first strut 20 has no attachment points. First strut 20 and second strut 22 are oriented at angles between 0 and 360 degrees with respect to the longitudinal axis. In a preferred embodiment, first strut 20 is at an angle of approximately 352 degrees (or –8 degrees), while second strut 22 is at an angle of approximately 346 degrees (or –14 degrees).

Referring now to FIGS. 5A and 5B, an expanded view of stent 10 is shown, according to a first preferred embodiment of the present invention, as shown in FIGS. 1-4. In FIG. 5A, first and second struts 20 and 22 are approximately equal in thickness, and attachment points 42 and 44 are not aligned along a longitudinal axis 16. In FIG. 5B, first and second struts have different thicknesses and attachment points 42 and 44 are aligned along a longitudinal axis 16, as described above with reference to FIG. 4. Cells 25 in the expanded state as shown in the preferred embodiments have a repeated pattern about the longitudinal axis. However, although cells 25 are characterized by a linearly asymmetric and eccentric geometrical configuration, they can also be considered to have rotational symmetry. In this manner, the size of the largest circle 28 (indicated in FIG. 5A and FIG. 5B by dashed lines) which can be inscribed in cells 25 is thereby reduced or minimized. Thus, better coverage is ensured preventing tissue prolapse, and better scaffolding for drug eluting coatings is available as well.

In addition, for the design shown in FIG. 5B, the particular location of attachment points 42 and 44, as well as the angle of second strut 22 prior to expansion, prevent foreshortening of the stent in the longitudinal direction upon expansion. As radial forces provided by a balloon (or in some other manner) push stent 10 from a crimped state to an expanded state, first struts 20 and joining segments 21 rotate, providing most of the expansion of stent 10. At the same time, second struts 22, attachment points 42 and 44, and connectors 24 do not move or move only slightly relative to one another, resulting in the pushing of attachment points 42 and 44 towards each other. Forces created by this movement cause sinusoidal connectors

24 to push outwardly on expansion rings 32, thereby separating them from each other, and thus compensating for foreshortening that may otherwise occur due to expansion of struts 20 and 22.

Referring now to FIGS. 6-8, another preferred embodiment of stent 10 is shown, in accordance with the present invention. FIG. 6 is a planar view of the pattern, FIG. 7 is a close up view of the pattern shown in FIG. 6, and FIG. 8 is a view of the pattern shown in FIGS. 6 and 7 after expansion. The geometric pattern shown in FIGS. 6-8 is similar in principle to the embodiment shown in FIGS. 1-5, and particularly FIGS. 4 and 5B showing narrow and wide first and second struts 20, 22 and showing longitudinally aligned attachment points 42, 44. However, additional features are provided, as follows. First and second struts 20 and 22 and joining segment 21 are arranged in a sinusoidal wave pattern around the circumference of ring section 32. In addition, each of first and second struts 20 and 22 is comprised of two portions: an upper curved portion 50 and a lower curved portion 52. Upper and lower curved portions 50 and 52 are connected at a point at which joining segment 21 connects struts 20 and 22 to each other. This configuration results in first strut 20 and second strut 22 each having a hole segment therethrough, labeled 46 and 48, respectively. This design enables more surface area coverage for scaffolding support with less metal than would otherwise be required. By reducing the amount of metal in this way, the risk of restenosis and other complications is reduced while still retaining the support of the vessel and stent integrity. An additional advantage of this design is that in a drug coated stent, as will be described in further detail hereinbelow, a more regular delivery of drugs is possible because of the more evenly distributed scaffolding area.

FIGS. 9-11 are schematic diagrams illustrating alternative exemplary preferred embodiments of the geometrical configuration of side hole 30 in an unexpanded state and in an expanded state.

In particular, FIGS. 9A, 10A and 11A are schematic diagrams illustrating three exemplary alternative preferred embodiments of side hole 30 of stent body 12 of stent 10, in an unexpanded state. As shown, side hole 30 in an unexpanded state may be elliptical, rectangular, hexagonal, as well other shapes. Outline schematics of the expanded states of side hole 30 corresponding to stent body 12 of FIGS. 9A, 10A and 11A are shown in FIGS. 9B, 10B and 11B, respectively. In the preferred

embodiments shown in FIGS. 9A-B and 10A-B, cells 25' in a region of side hole 30 are of a different geometrical configuration than the rest of cells 25 of stent body 12, so as to accommodate the shape of side hole 30. The "region" of side hole 30 can include, but is not limited to, cells surrounding side hole 30, cells contiguous to side hole 30, and cells located on expansion rings 32 which include side hole 30. In an alternative embodiment, as shown in FIGS. 11 A and B, cells 25 in a region of side hole 30 are of the same geometrical configuration as the rest of cells 25 of stent body 12, since the shape of side hole 30 does not need to be accommodated in this embodiment. An advantage of the design shown in FIGS. 11A and 11B is that cells in the region of side hole 30 are still able to provide the support needed in that area, which would not be the case if cells are unduly large or out of proportion.

In the present invention, expansion of stent body 12 results in side hole 30 expanding automatically into an opening with a diameter approximately equal to or less than the long axis of side hole 30 when in an unexpanded state. Side hole 30 allows access to a side branch or branch lumen, located in the region of a vessel bifurcation, and may be circular, oval, elliptical, or any other shape that would enable access to the side branch.

Side hole 30 may be located anywhere along stent body 12, including along the proximal or distal end of stent body 12 of stent 10. In a preferred embodiment, side hole 30 is located in the center of the length of stent body 12. In other embodiments, more than one side hole 30 may be included at various locations along the length of stent body 12. As shown in FIGS. 9-11, the geometric configuration of side hole 30 is larger in size and different in shape than remaining cells 25. Advantages of providing a relative large side hole 30 or side holes as compared to the size of cells 25 include the ability to provide arterial wall support and uniform coverage for potential drug delivery in the areas of stent coverage without jailing the ostium of the side branch. The presence of greater wall coverage reduces the possibility of tissue prolapse through the cells.

The above-described geometrical configuration of struts 20, 22 and connectors 24 preferably allows side hole 30 to change to an approximately circular shape after expansion of stent body 12. Other embodiments of a side hole 30 in accordance with the present invention may be contemplated, including those disclosed in U.S. Patent

Application Serial No. 60/404,756, filed on August 21, 2002, and incorporated herein by reference in its entirety.

In a particular embodiment of the stent of the present invention, a stent 10 specified for a 3.0 mm main vessel having a 2.5 mm diameter side branch will have a main tube or cylinder diameter of 1-2 mm in a crimped state. In a preferred embodiment, the outer diameter is approximately 1.4 mm. In an alternative preferred embodiment, the stent with a side hole will have two diameters in the crimped state: one distal to the side hole 30 and one proximal to the side hole 30. In one embodiment, the distal portion is relatively circular, with an unexpanded diameter of 1-2 mm. In a preferred embodiment, the crimped diameter of the distal portion is approximately 1.4 mm. In this embodiment, the proximal portion is relatively oval so as to accommodate a side sheath, and thus has two outer diameters: The minor diameter is 1-2 mm, and the major diameter is 1.5-2.5 mm. In a preferred embodiment, the minor diameter of the proximal portion of the stent is approximately 1.4 mm and the major diameter is approximately 1.8 mm. It should be readily apparent that many different diameters are envisioned, as long as the stent and side opening are sized so as to fit the main and branch vessel. The main tube or cylinder diameter is expanded to about 3.0 mm to match the main vessel diameter. Upon stent expansion, side hole 30 expands and/or contracts so that side hole 30 has a generally circular shape. In a particular embodiment, side hole 30 is expanded to a diameter of up to 2.5 mm, to match the diameter of the side branch.

In another preferred embodiment, a stent 10 is specified for a 3.5 mm main vessel having a 3.0 mm diameter side branch, with crimped state measurements approximately equal to those disclosed for the 3.0 mm main vessel diameter stent described above. The main tube diameter is expanded to about 3.5 mm to match the main vessel diameter, and side hole 30 is expanded to a diameter of up to 3.0 mm, to match the diameter of the side branch. The difference in expansion measurements is achieved by differences in dimensions of struts and connectors. It will be appreciated by those skilled in the art that the above example is not intended to limit the scope of the present invention. Different geometrical configurations and dimensions may be used to produce a variety of stents 10, stent bodies 12, and side holes 30 consistent with the above description. For example, stent 10 may have a smaller expanded diameter than side hole 30.

The cellular geometrical configuration of stent body 12 as illustrated in FIGS. 1 - 16, is suitable for optimally performing two basic functions of a non-conventional or special stent following stent expansion in a vessel, that is (i) forming sufficiently small sized cells for optimally supporting a vessel wall, thereby preventing or reducing tissue prolapse, and (ii) forming sufficiently large side holes for providing accessibility of blood flow and of a potentially future implanted branch stent to branch vessels, thereby preventing stent jailing.

FIG. 12 is a side view of an embodiment of a catheter having a stent that may be deployed within a vessel such that the side hole 30 of the stent 10 is in registry with an ostium of a branch vessel in the region of a vessel bifurcation. The construction and operation of catheters suitable for the purpose of the present invention are further described in U.S. Patent Application No. 09/663,111, filed September 15, 2000, which is a continuation-in-part of U.S. Patent Application No. 09/614,472, filed July 11, 2000, which is a continuation-in-part of U.S. Patent Application Nos. 09/325,996, filed June 4, 1999, and 09/455,299, filed December 6, 1999, all of which are incorporated herein by reference in their entireties.

Briefly, a side sheath is attached or placed alongside a main catheter, for receiving a side branch guidewire therethrough. A main guidewire is inserted into a main blood vessel, after which the catheter system is advanced over the main guidewire. The side branch guidewire is either preloaded within the side sheath, or is placed through the side sheath once the catheter system is in place. A balloon is situated on the catheter, with the stent of the present application crimped thereon. The side sheath is placed between the balloon and the stent, exiting through side hole 30. It is for this reason that the proximal portion of stent body 12 may be wider in diameter than the distal region of stent body 12 in its crimped state. In the version of the catheter system in which the side sheath is attached, the point of attachment may vary. In preferred embodiments, the point of attachment is approximately 5-15 cm proximal to the balloon. In an exemplary preferred embodiment, the point of attachment is approximately 10 cm proximal to the balloon.

As the catheter system is advanced into the main vessel, the side sheath is positioned within the branch vessel so that the side branch guidewire can enter the branch vessel. The side sheath, when attached to the catheter, also serves to align side hole 30 with the ostium of a branch vessel, by causing the stent to be turned so that

side hole 30 faces the ostium. Thus, the system can be considered to have self-correcting rotational alignment, thereby providing optimum functionality and coverage of the diseased vessel.

One particular application for the use of a stent with a side hole such as the one described above is for localized drug delivery. For example, the stent device of the present invention may include a drug or drug compound depot provided in or on the stent body for the treatment of restenosis.

As used herein, the term "depot" describes a store of a drug or drug compound designed to retain and thereafter release the drug or drug compound.

The drug or drug compound depot of the stent device of the present invention is preferably designed capable of controllably releasing the drug or drug compound. Hence, the depot of the present invention can be made of any material that can entrap, encapsulate, adhere or otherwise retain and controllably release the drug or drug compound.

Preferably, the depot of the present invention is composed of one or more biocompatible polymer(s) loaded with the drug or drug compound. Preferably, the biocompatible polymer utilized minimizes irritation to the wall of the lumen where the stent is implanted.

Several loading configurations are envisaged by the present invention.

The drug or drug compound can be, for example, molded into the polymer, entrapped or encapsulated within the polymer, covalently attached to the polymer, physically adhered to the polymer or otherwise incorporated into the biocompatible polymer.

The biocompatible polymer can be either a biostable polymer or a biodegradable polymer, depending on the desired rate of release or the desired degree of polymer stability under physiological conditions.

Biodegradable polymers that are usable in the context of the present invention include, without limitation, poly(L-lactic add), polycaprolactone, poly(lactide-co-glycolide), poly(hydroxybutyrate), poly(hydroxybutyrate-co-valerate), polydioxanone, polyorthoester, polyanhydride, poly(glycolic acid), poly(D,L-lactic acid), poly(glycolic acid-co-trimethylene carbonate), polyphosphoester, polyphosphoester urethane, poly(amino acids), cyanoacrylates, poly(trimethylene carbonate), poly(iminocarbonate), copoly(ether-esters) (e.g. PEO/PLA), polyalkylene

oxalates, polyphosphazenes and biomolecules such as fibrin, fibrinogen, cellulose, starch, collagen and hyaluronic acid.

Biostable polymers that are usable in the context of the present invention include, without limitation, polyurethanes, silicones, polyesters, polyolefins, polyisobutylene, ethylene-alphaolefin copolymers; acrylic polymers and copolymers, vinyl halide polymers and copolymers, such as polyvinyl chloride; polyvinyl ethers, such as polyvinyl methyl ether; polyvinylidene halides, such as polyvinylidene fluoride and polyvinylidene chloride; polyacrylonitrile, polyvinyl ketones; polyvinyl aromatics, such as polystyrene, polyvinyl esters, such as polyvinyl acetate; copolymers of vinyl monomers with each other and olefins, such as ethylene-methyl methacrylate copolymers, acrylonitrile-styrene copolymers, ABS resins, and ethylene-vinyl acetate copolymers; polyamides, such as Nylon 66 and polycaprolactam; alkyd resins; polycarbonates; polyoxymethylenes; polyimides; polyethers; epoxy resins; polyurethanes; rayon; rayon-triacetate; cellulose, cellulose acetate, cellulose butyrate; cellulose acetate butyrate; cellophane; cellulose nitrate; cellulose propionate; cellulose ethers; and carboxymethyl cellulose.

The depot is present either in or on the stent body. The position of the depot with respect to the stent body depends on various parameters, such as the material of which the stent body is fabricated, its permeability, the efficacy of the depot in retaining the drug or drug compound, and the desired release rate and duration of the drug or drug compound.

Preferably, the depot is formed from an external surface of the stent body. In such cases, the drug or drug compound depot can be formed by a coating of the stent device. Specifically, both the stent body 12 and side hole 30 can be coated, or only one of these portions can be coated. In addition, different drugs may be placed around side hole 30 than around the rest of the stent. Alternatively, a different dosage of the same drug may be placed around side hole 30 as compared to the rest of the stent. All different combinations and permutations are possible and are envisioned. One or more drugs selected from the group consisting of anti-thrombogenic agents, anti-inflammatory agents, anti-proliferative agents, and anti-migration agents may be incorporated into polymer(s) and applied to stent body 12 and side hole 30, or only on one of these portions.

The drug or drug compound is entrapped, encapsulated, adhered or otherwise retained in the depot, in a manner suitable for controllable release of the drug or drug compound therefrom. The drug or drug compound can, for example, be molded into a biocompatible polymer, which is thereafter attached to a stent body, to thereby produce a stent device according to the present invention.

Examples of drugs to be used in stent drug-eluting technologies are Paclitaxol, Rapamycin, or drugs in the family of HDAC inhibitors. Further details pertaining to an HDAC inhibitor, its use and stents incorporating same are disclosed in a U.S. Provisional Patent Application assigned to a common assignee of the present invention, filed July 24, 2002, Attorney Docket No. 03/23768, entitled "STENTS CAPABLE OF CONTROLLABLY RELEASING HISTONE DEACETYLASE INHIBITORS," incorporated by reference herein in its entirety.

It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination.

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims. All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention.

WHAT IS CLAIMED IS:

1. A stent having a longitudinal axis, the stent comprising:

a first ring section made up of expansion segments arranged circumferentially around the stent, each of said expansion segments comprising a first strut and a second strut joined by a joining segment, wherein the joining segment is alternatingly located at one end of said first and second struts for one expansion segment, and at another end of said first and second struts for another expansion segment, and wherein said first strut is not parallel to the longitudinal axis of the stent;

a second ring section made up of expansion segments arranged circumferentially around the stent, each of said expansion segments comprising a first strut and a second strut joined by a joining segment, wherein the joining segment is alternatingly located at one end of said first and second struts for one expansion segment, and at another end of said first and second struts for another expansion segment, and wherein the first strut is not parallel to the longitudinal axis of the stent; and

a series of sinusoidal connectors for connecting said first ring section to said second ring section, said connectors having a first section, a second section and a third section, each of said connectors having a first end and a second end, wherein said first end is connected to a second strut of an expansion segment of said first ring forming a first connection point, and said second end is connected to a second strut of an expansion segment of said second ring forming a second connection point, and wherein said first ring section is offset from said second ring section and wherein said second section of said connector is not perpendicular to the longitudinal axis of the stent.

2. A stent as in claim 1, wherein said second strut of said first ring section is non-parallel to the longitudinal axis.

3. A stent as in claim 1, wherein said second strut of said second ring section is non-parallel to the longitudinal axis.

4. A stent as in claim 1, wherein said first end and said second end of said connectors are aligned with the longitudinal axis.

5. A stent as in claim 1, wherein said struts, joining segments and connectors form cells.

6. A stent as in claim 5, wherein said cells are linearly asymmetrical.

7. A stent as in claim 5, wherein said cells are rotationally symmetrical.

8. A stent as in claim 5, further comprising a side hole, said side hole being different than said cells.

9. A stent as in claim 8, wherein said difference between said side hole and said cells is shape.

10. A stent as in claim 8, wherein said difference between said side hole and said cells is size.

11. A stent as in claim 10, wherein said side hole is larger than said cells upon expansion of the stent.

12. A stent as in claim 8, wherein said stent has different diameters proximal to and distal to said side hole.

13. A stent as in claim 8, further comprising side hole cells in a region of said side hole, wherein said side hole cells are of a different geometrical configuration than said cells.

14. A stent as in claim 8, further comprising side hole cells in a region of said side hole, wherein said side hole cells are of the same geometrical configuration as said cells.

15. A stent as in claim 1, wherein the first struts are wider than the second struts.

16. A stent as in claim 1, wherein said joining segments are "C" shaped.

17. A stent as in claim 1, wherein said joining segments are non-parallel to a circumferential axis.

18. A stent as in claim 1, wherein said connectors comprise a relatively straight middle portion, and wherein said middle portion is non-parallel to a circumferential axis.

19. A stent as in claim 1, wherein said first strut is non-parallel to said second strut.

20. A stent as in claim 1, wherein said first and second struts are curved.

21. A stent as in claim 1, wherein said first and second struts are comprised of an upper curved portion, and a lower curved portion connected to the upper curved portion.

22. A stent as in claim 1, further comprising a drug placed thereon.

23. A stent as in claim 22, wherein said drug is an HDAC inhibitor.

24. A stent as in claim 22, wherein said drug is incorporated into a biocompatible polymer.

25. A stent as in claim 1 wherein said first and second connection points are aligned with the longitudinal axis.

26. A stent as in claim 1, wherein upon expansion, said second struts, joining segments and attachments remain substantially in alignment with one another.

27. A stent having a longitudinal axis, the stent comprising:

a first ring section made up of expansion segments arranged circumferentially around the stent, each of said expansion segments comprising a first strut and a second strut joined by a joining segment, wherein the joining segment is alternatingly located at one end of said first and second struts for one expansion segment, and at another end of said first and second struts for another expansion segment;

a second ring section made up of expansion segments arranged circumferentially around the stent, each of said expansion segments comprising a first strut and a second strut joined by a joining segment, wherein the joining segment is alternatingly located at one end of said first and second struts for one expansion segment, and at another end of said first and second struts for another expansion segment; and

a series of connectors for connecting said first ring section to said second ring section, each of said connectors having a first end and a second end, wherein said first end is connected to a second strut of an expansion segment of said first ring forming a first connection point, and said second end is connected to a second strut of an expansion segment of said second ring forming a second connection point, and wherein an imaginary line connecting said first connection point and said second connection point is parallel to the longitudinal axis.

28. A stent as in claim 27, wherein said first struts are narrower than said second struts.

29. A stent as in claim 27, wherein said struts are non-parallel to the longitudinal axis.

30. A stent as in claim 27, wherein the joining segments are "C" shaped.

31. A stent as in claim 27, wherein said connectors are sinusoidal.

32. A stent as in claim 27, wherein said first ring section is offset from said second ring section.

33. A stent as in claim 27, wherein said struts, joining segments and connectors form cells.

34. A stent as in claim 33, wherein said cells are linearly asymmetrical.

35. A stent as in claim 33, wherein said cells are rotationally symmetrical.

36. A stent as in claim 33, further comprising a side hole, said side hole being different than said cells.

37. A stent as in claim 36, wherein said difference between said side hole and said cells is shape.

38. A stent as in claim 36, wherein said difference between said side hole and said cells is size.

39. A stent as in claim 38, wherein said side hole is larger than said cells upon expansion of the stent.

40. A stent as in claim 36, further comprising side hole cells surrounding said side hole, wherein said side hole cells are of a different geometrical configuration than said cells.

41. A stent as in claim 36, further comprising side hole cells in a region of said side hole, wherein said side hole cells are of the same geometrical configuration as said cells.

42. A stent as in claim 36, wherein said stent has different diameters proximal to and distal to said side hole.

43. A stent as in claim 27, wherein said connectors comprise a relatively straight middle portion, and wherein said middle portion is non-parallel to a circumferential axis.

44. A stent as in claim 27, wherein said joining segments are non-parallel to a circumferential axis.

45. A stent as in claim 27, wherein said first strut is non-parallel to said second strut.

46. A stent as in claim 27, wherein said first and second struts are curved.

47. A stent as in claim 27, wherein said first and second struts are each comprised of an upper curved portion and a lower curved portion connected to the upper curved portion.

48. A stent as in claim 27, further comprising a drug placed thereon.

49. A stent as in claim 48, wherein said drug is an HDAC inhibitor.

50. A stent as in claim 48, wherein said drug is incorporated into a biocompatible polymer.

51. A stent as in claim 27, wherein upon expansion, said second struts, joining segments and attachments remain substantially in alignment with one another.

52. A stent having a longitudinal axis, the stent comprising:

a first ring section made up of expansion segments arranged circumferentially around the stent, each of said expansion segments comprising a first strut and a second strut joined by a joining segment, wherein the joining segment is alternatingly located at one end of said first and second struts for one expansion segment, and at another end of said first and second struts for another expansion segment;

a second ring section made up of expansion segments arranged circumferentially around the stent, each of said expansion segments comprising a first strut and a second strut joined by a joining segment, wherein the joining segment is alternatingly located at one end of said first and second struts for one expansion segment, and at another end of said first and second struts for another expansion segment;

a series of connectors for connecting said first ring section to said second ring section, each of said connectors having a first end and a second end, wherein said first end is connected to a second strut of an expansion segment of said first ring forming a first connection point, and said second end is connected to a second strut of an expansion segment of said second ring forming a second connection point, wherein cells are formed by said first and second struts, said joining segments and said connectors; and

a side hole located along said stent body, wherein said side hole is different than said cells.

53. A stent as in claim 52, wherein said first struts are non-parallel to the longitudinal axis.

54. A stent as in claim 52, wherein said second struts are non-parallel to the longitudinal axis.

55. A stent as in claim 52, wherein the joining segments are "C" shaped.

56. A stent as in claim 52, wherein said connectors are sinusoidal.

57. A stent as in claim 52, wherein said first ring section is offset from said second ring section.

58. A stent as in claim 52, wherein said difference between said side hole and said cells is shape.

59. A stent as in claim 52, wherein said difference between said side hole and said cells is size.

60. A stent as in claim 59, wherein said side hole is larger than said cells upon expansion of the stent.

61. A stent as in claim 52, wherein said stent has different diameters proximal to and distal to said side hole.

62. A stent as in claim 52, wherein the first struts are wider than the second struts.

63. A stent as in claim 52, wherein said joining segments are non-parallel to a circumferential axis.

64. A stent as in claim 52, further comprising side hole cells surrounding said side hole, wherein said side hole cells are of a different geometrical configuration than said cells.

65. A stent as in claim 52, further comprising side hole cells in a region of said side hole, wherein said side hole cells are of the same geometrical configuration as said cells.

66. A stent as in claim 52 wherein said first and second connection points are aligned with the longitudinal axis.

67. A stent as in claim 52, wherein said connectors comprise a relatively straight middle portion, and wherein said middle portion is non-parallel to a circumferential axis.

68. A stent as in claim 52, wherein said first strut is non-parallel to said second strut.

69. A stent as in claim 52, wherein said first and second struts are curved.

70. A stent as in claim 52, wherein said first and second struts are comprised of an upper curved portion, and a lower curved portion connected to the upper curved portion.

71. A stent as in claim 52, further comprising a drug placed thereon.

72. A stent as in claim 71, wherein said drug is an HDAC inhibitor.

73. A stent as in claim 71, wherein said drug is incorporated into a biocompatible polymer.

74. A stent as in claim 52, wherein said cells are linearly asymmetrical.

75. A stent as in claim 52, wherein said cells are rotationally symmetrical.

76. A stent as in claim 52, wherein upon expansion, said second struts, joining segments and attachments remain substantially in alignment with one another.

77. A stent comprising:

a stent body; and

a lumen,

wherein the stent body has a ring section made up of expansion segments arranged circumferentially around the stent, each of said expansion segments comprising a first strut and a second strut joined by a joining segment, wherein the joining segment is alternatingly located at one end of said first and second struts for one expansion segment, and at another end of said first and second struts for another expansion segment, and wherein said first and said second struts are comprised of an upper curved portion, and a lower curved portion connected to the upper curved portion.

78. A stent as in claim 77, further comprising a second ring section made up of expansion segments arranged circumferentially around the stent, each of said expansion segments comprising a first strut and a second strut joined by a joining segment, wherein the joining segment is alternatingly located at one end of said first and second struts for one expansion segment, and at another end of said first and second struts for another expansion segment, and wherein said first and said second struts are comprised of an upper curved portion, and a lower curved portion connected to the upper curved portion; and

a series of connectors for connecting said ring section to said second ring section, each of said connectors having a first end and a second end, wherein said first end is connected to a second strut of an expansion segment of said ring section forming a first connection point, and said second end is connected to a second strut of an expansion segment of said second ring section forming a second connection point.

79. A stent as in claim 78, wherein cells are formed by said first and second struts, said joining segments and said connectors, and further comprising a side hole located along said stent body, wherein said side hole is different than said cells.

80. A stent as in claim 79, wherein said cells are linearly asymmetrical.

81. A stent as in claim 79, wherein said cells are rotationally symmetrical.

82. A stent as in claim 77, wherein said joining segments are "C" shaped.

83. A stent as in claim 77, wherein said first struts are non-parallel to the longitudinal axis.

84. A stent as in claim 77, wherein said second struts are non-parallel to the longitudinal axis.

85. A stent as in claim 77, wherein said first struts are narrower than said second struts.

86. A stent as in claim 77, wherein said connectors are sinusoidal.

87. A stent as in claim 77, wherein said ring section is offset from said second ring section.

88. A stent as in claim 79, wherein said difference between said side hole and said cells is shape.

89. A stent as in claim 79, wherein said difference between said side hole and said cells is size.

90. A stent as in claim 89, wherein said side hole is larger than said cells upon expansion of the stent.

91. A stent as in claim 79, wherein said stent has different diameters proximal to and distal to said side hole.

92. A stent as in claim 77, wherein said joining segments are non-parallel to a circumferential axis.

93. A stent as in claim 79, further comprising side hole cells in a region of said side hole, wherein said side hole cells are of a different geometrical configuration than said cells.

94. A stent as in claim 79 further comprising side hole cells in a region of said side hole, wherein said side hole cells are of the same geometrical configuration as said cells.

95. A stent as in claim 78, wherein said connectors comprise a relatively straight middle portion, and wherein said middle portion is non-parallel to a circumferential axis.

96. A stent as in claim 77, wherein said first strut is non-parallel to said second strut.

97. A stent as in claim 77, wherein said first and second struts are curved.

98. A stent as in claim 77, further comprising a drug placed thereon.

99. A stent as in claim 98, wherein said drug is an HDAC inhibitor.

100. A stent as in claim 98, wherein said drug is incorporated into a biocompatible polymer.

101. A stent as in claim 78 wherein said first and second connection points are aligned with the longitudinal axis.

102. A stent as in claim 77, wherein upon expansion, said second struts, joining segments and attachments remain substantially in alignment with one another.

103. A stent having a configuration of cells, said cells comprised of struts and connectors, wherein said cells are rotationally symmetrical and linearly asymmetrical, and wherein said struts and connectors are arranged in an eccentric pattern.

104. A stent as in claim 103, further comprising a side hole, wherein said side hole is larger than any of said cells.

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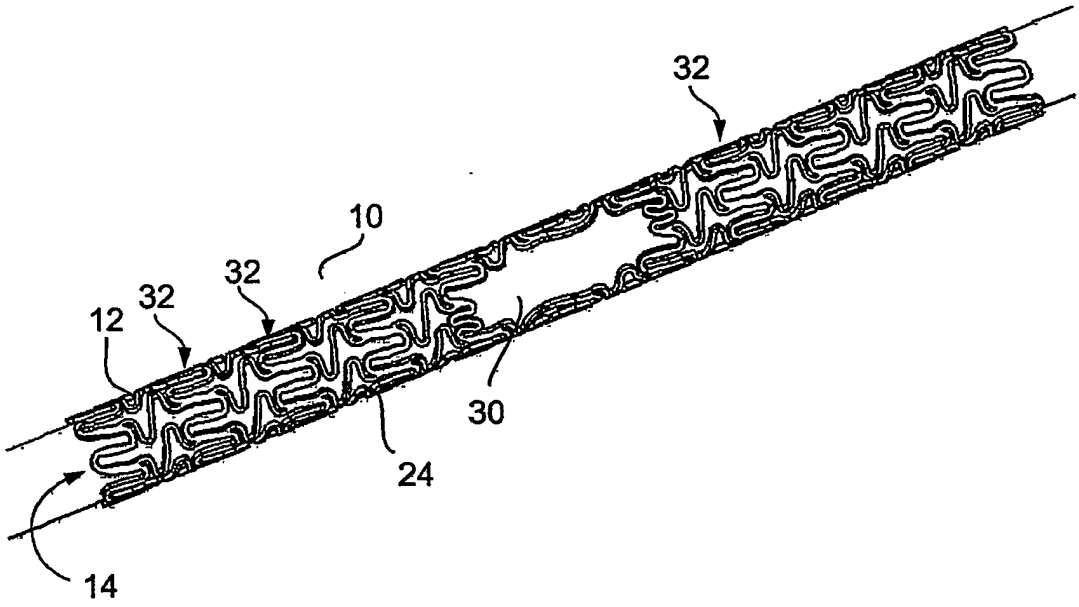

Fig. 1a

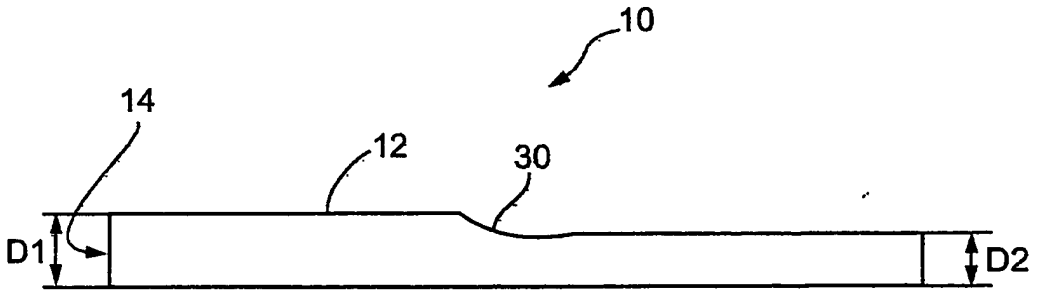

Fig. 1b

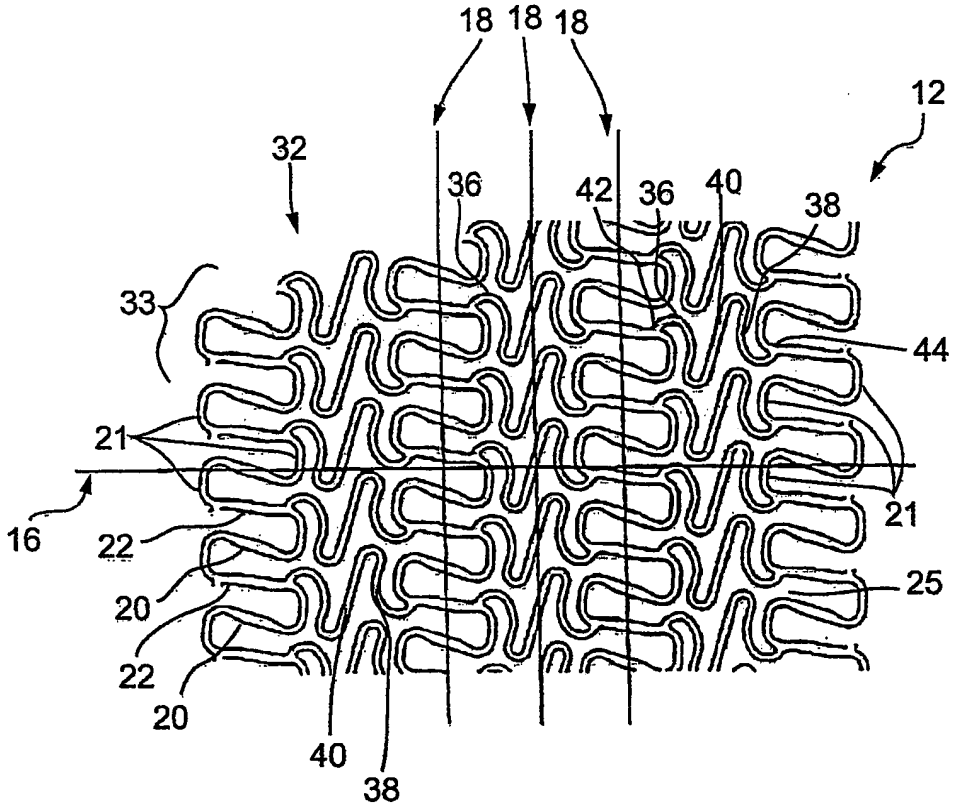

Fig. 2

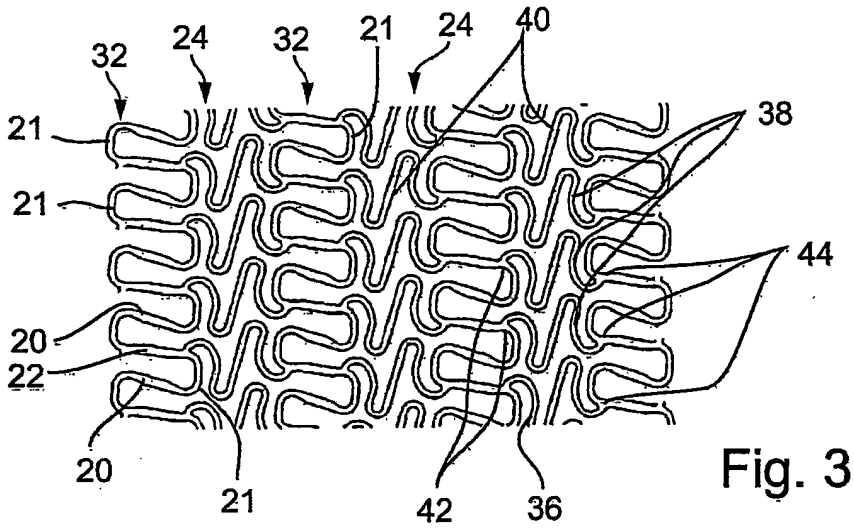

Fig. 3a

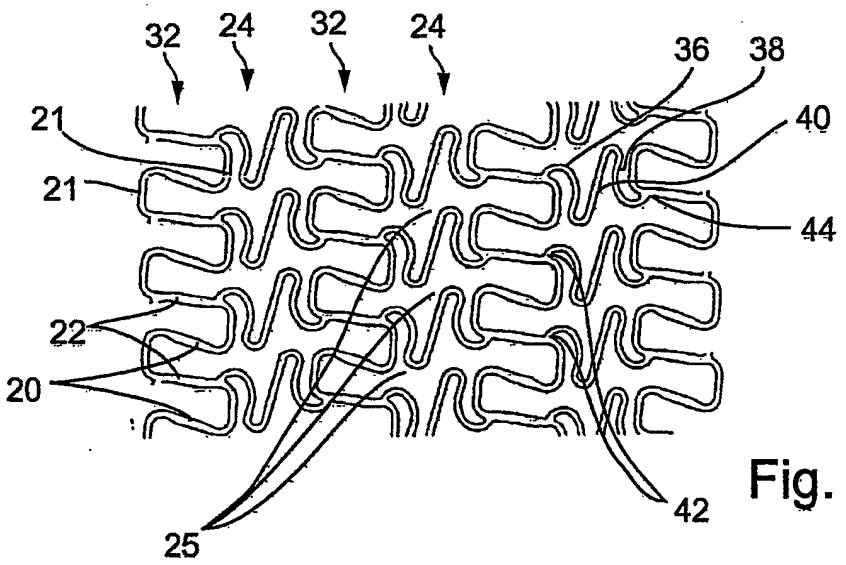

Fig. 3b

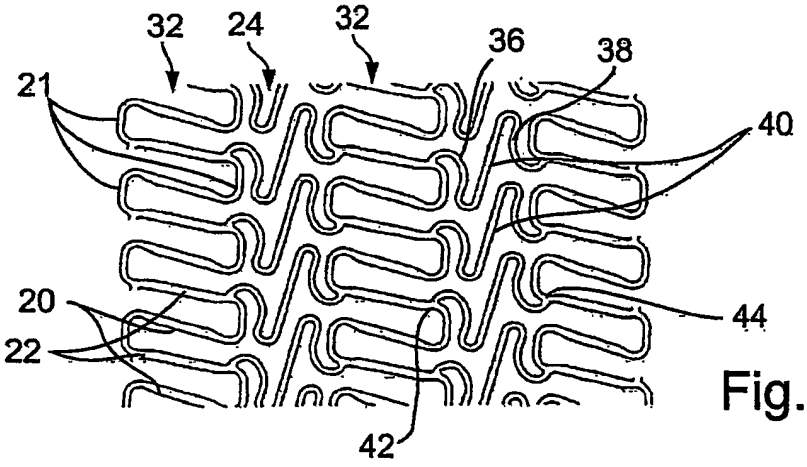

Fig. 3c

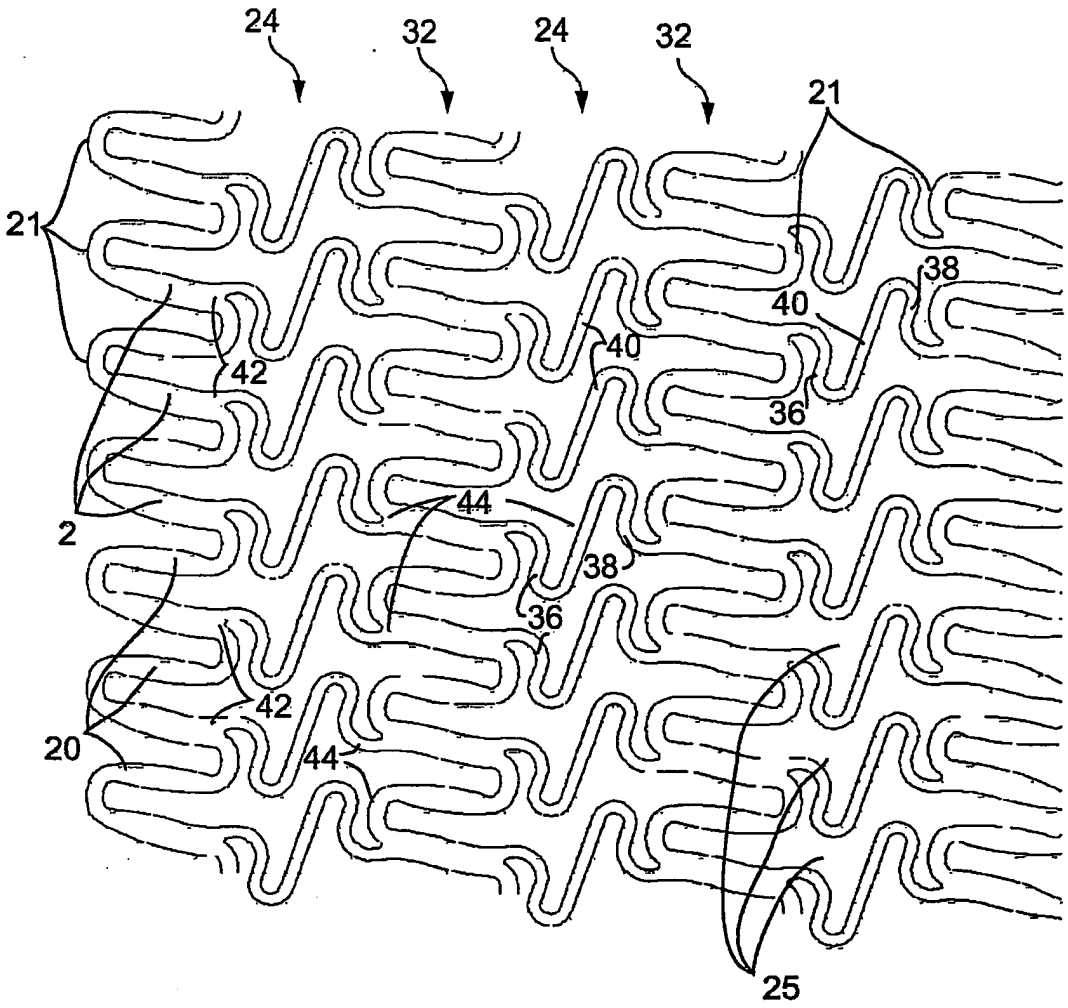

Fig. 4

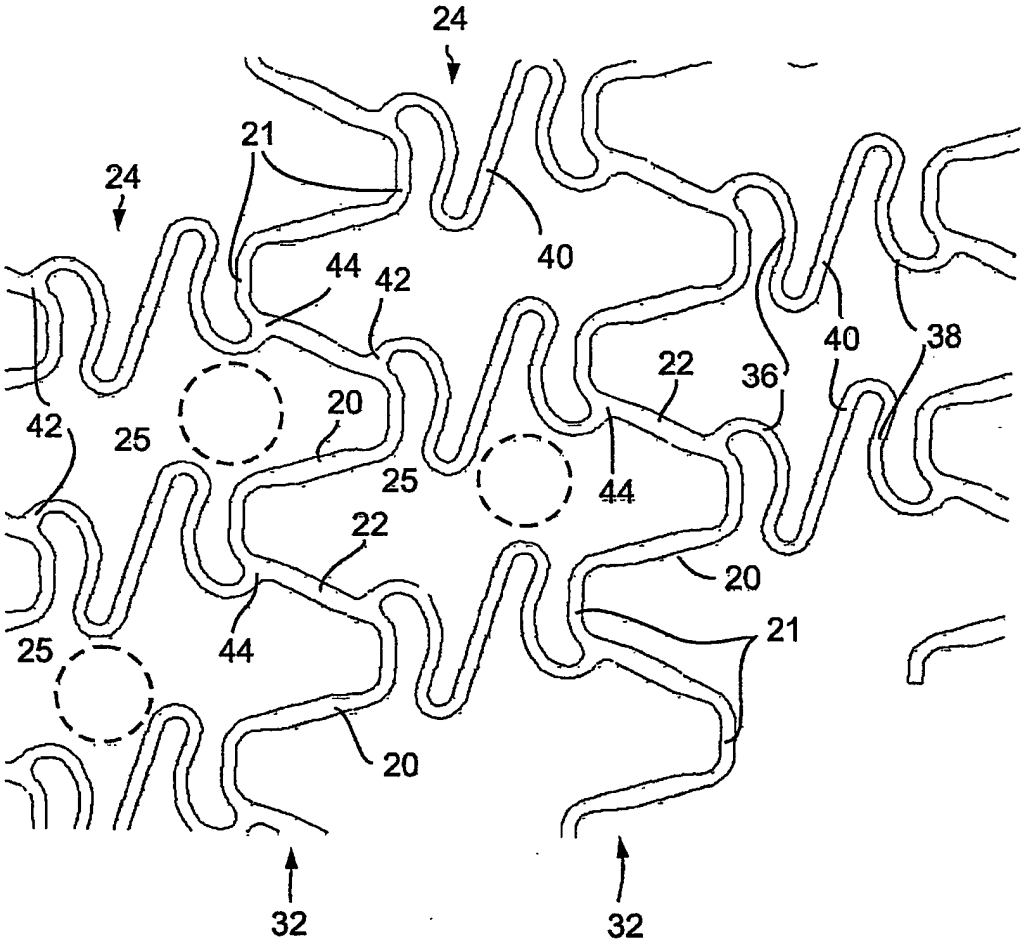

Fig. 5a

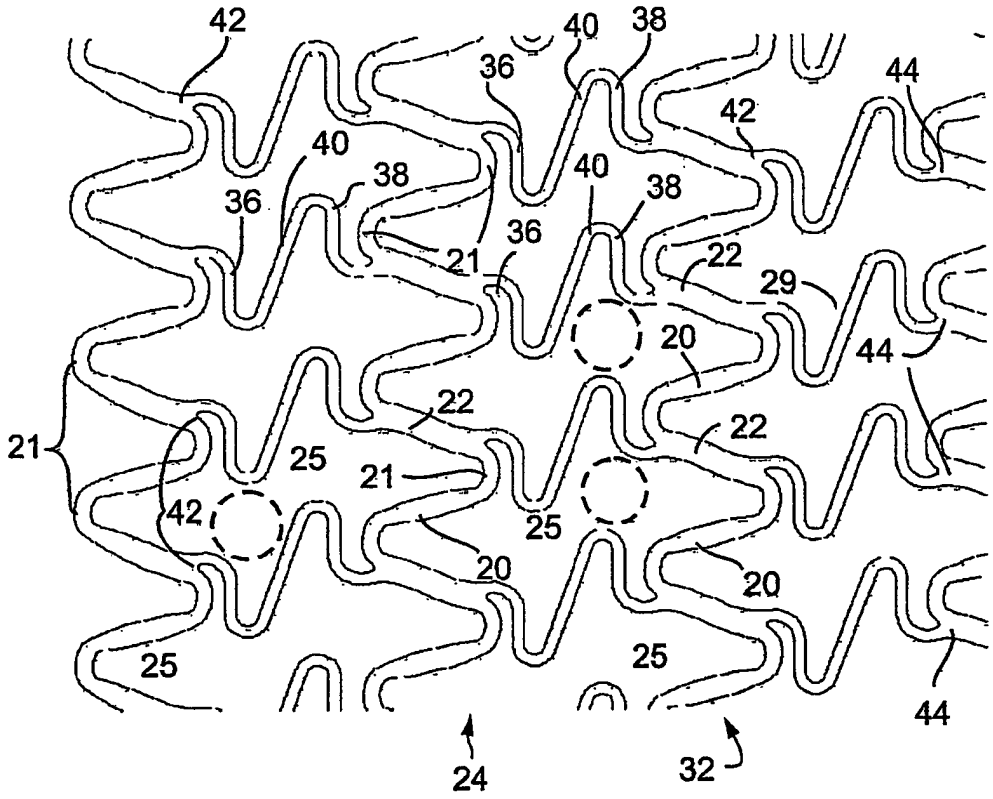
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Fig. 5b

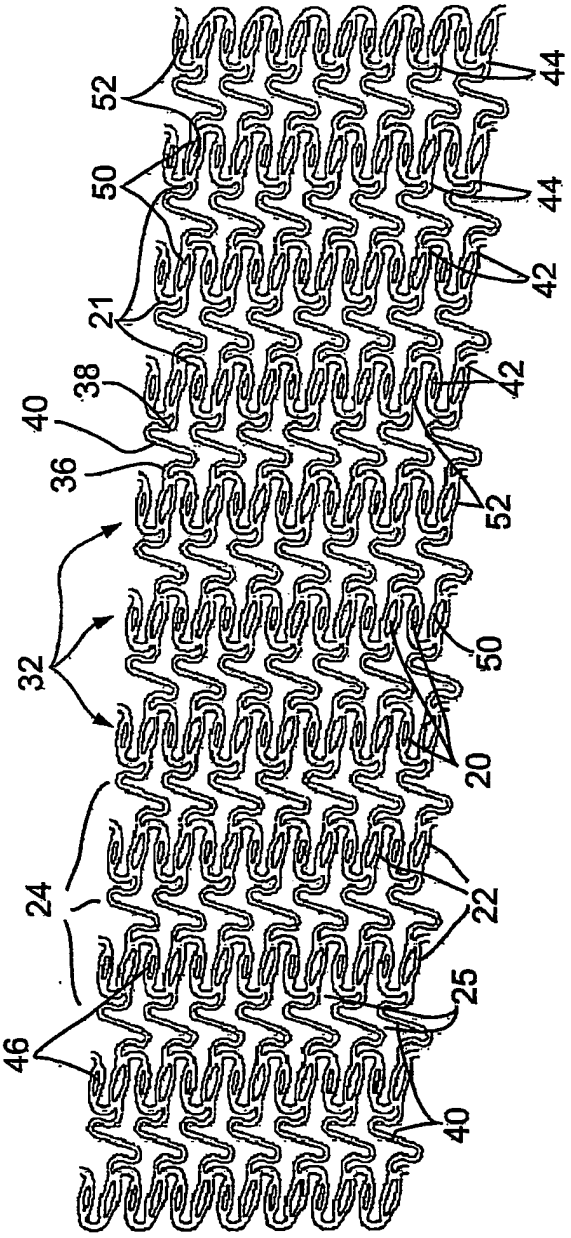

Fig. 6

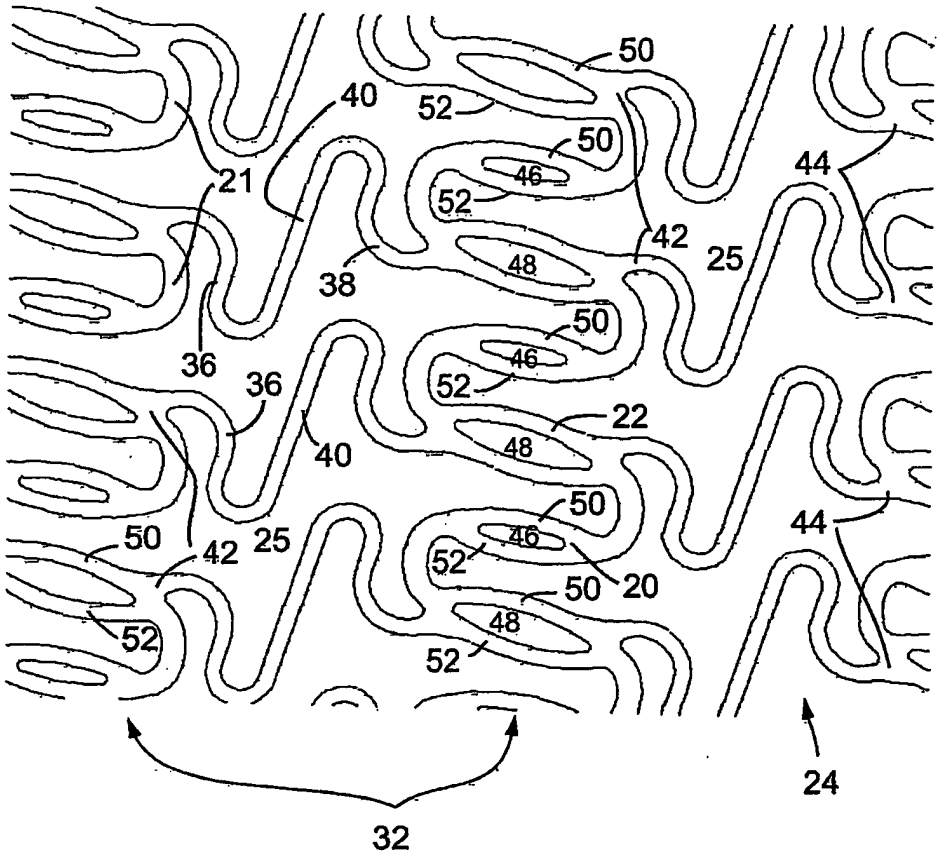
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Fig. 7

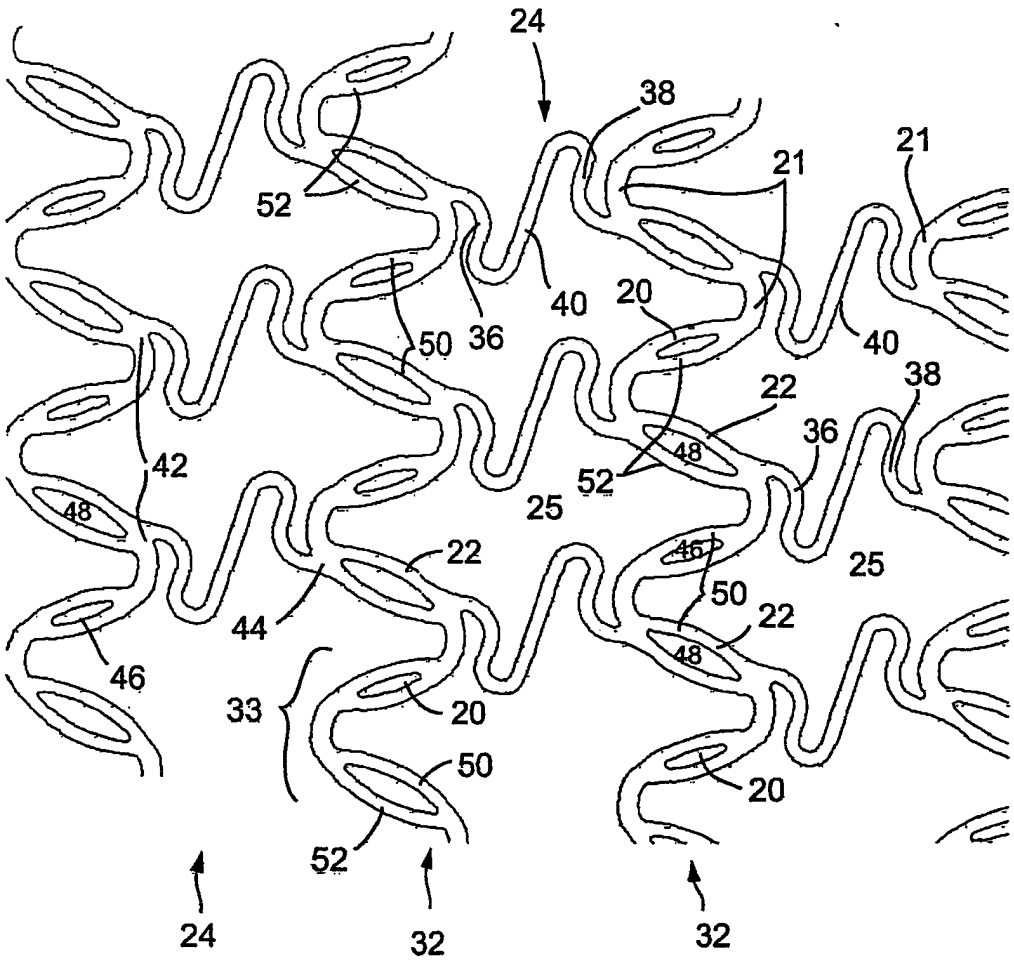
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Fig. 8

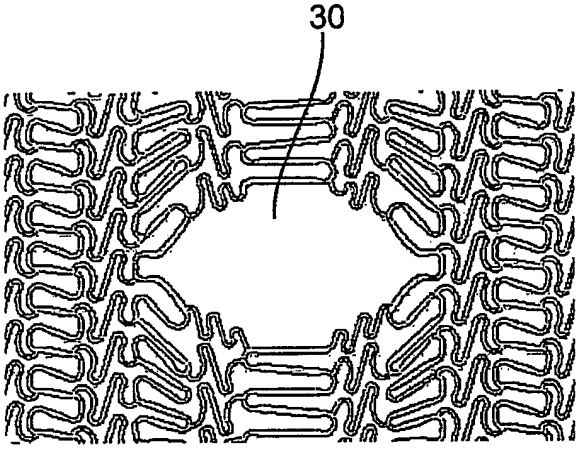

Fig. 9a

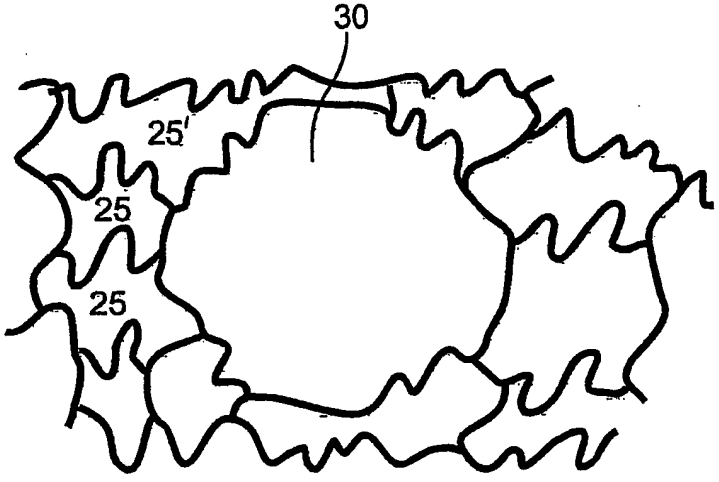

Fig. 9b

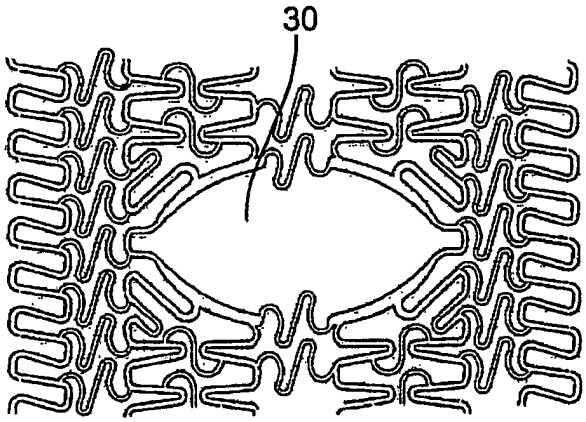

Fig. 10a

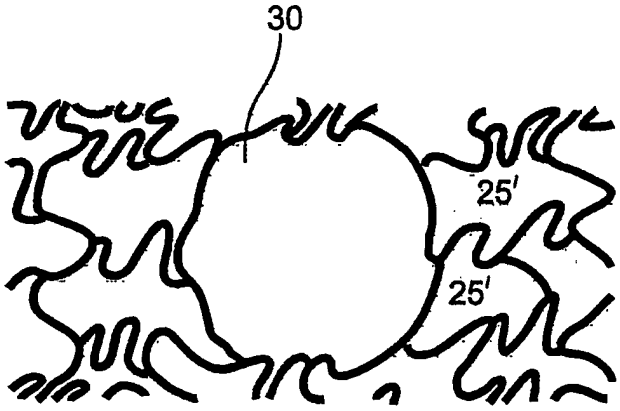

Fig. 10b

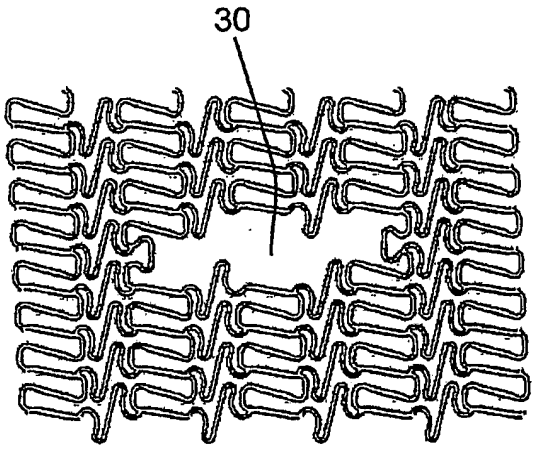

Fig. 11a

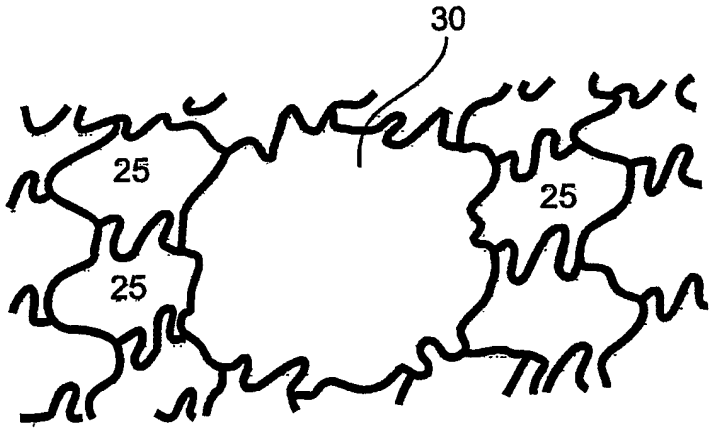

Fig. 11b

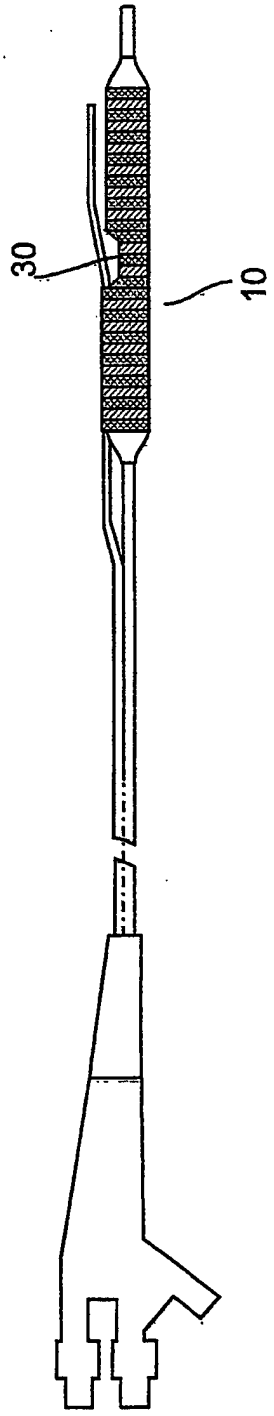

Fig. 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL02/00840

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61 F 2/06
US CL : 623/1.15
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 623/1.15,1.16,1.3,1.39,1.42

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X —, E Y	US 6,488,703 B1 (KVEEN et al) 03 December 2002 (03.12.2002), see col. 3, line 5- col. 4, line 40 and Figs. 1-9.	1-6,16-19,26,27,29-34,43-45,51,77,78,82-84,86,87,95,96,101,102 --- 8-11,13,36-40,52-67,63,66-68,74,76,79
Y	US 6,258,116 B1 (HOJEIBANE) 10 July 2001 (10.07.2001), col. 8, lines 45+, all Figs, especially Fig. 14.	8-11,13,36-40,52,58-60,64,79,80,88-90,92,93
X —, P Y	US 6,361,555 B1 (WILSON) 26 March 2002 (26.03.2002), col. 6, lines 34-49, col. 8, 37-41and Figs. 7A-8.	103,104 --- 22,24,48,50,71,73,98,100

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 March 2003 (12.03.2003)	22 MAY 2003
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Kamrin R. Landrem Diane Smith Telephone No. 703-308-0858

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